

JUL 02 2004

**Bard Urological Division**  
C. R. Bard, Inc.  
8195 Industrial Blvd.  
Covington, GA 30014



## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

### A. SUBMITTER INFORMATION:

Submitter's Name:	C. R. Bard, Inc., Urological Division
Address:	8195 Industrial Blvd. Covington, GA 30014
Contact Person:	John C. Knorpp
Contact Person's Telephone Number:	770-784-6451
Contact Person's Fax:	770-784-6419
Date of Preparation:	June 11, 2004

### B. DEVICE NAME:

Trade Name(s):	SourceLink™ Brachytherapy Seeding Spacer Links
Common / Usual Name:	Brachytherapy seeding spacer links
Classification Names:	(Accessory to) Source, Brachytherapy, Radionuclide 21 CFR 892.5730

### C. PREDICATE DEVICE NAME:

**Trade Names:** SourceLink™ Brachytherapy Seeding Spacer Links

### D. DEVICE DESCRIPTION:

SourceLink™ Brachytherapy Seeding Spacer Links have been designed to accurately space seeds in 0.5cm increments center-to-center during brachytherapy implant procedures. Seeds are 0.8mm in diameter and friction fit into the open female ends of the SourceLink™ Brachytherapy Seeding Spacer Links. The friction fit ensures the spacing between seeds will be accurately maintained during the implant procedure. The SourceLink™ Brachytherapy Seeding Spacer Links are compatible by design with commonly used implant needles.

### E. INTENDED USE:

SourceLink™ Brachytherapy Seeding Spacer Links are intended for spacing and linking brachytherapy seeds to be used in brachytherapy procedures.

**F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:**

The subject SourceLink™ Brachytherapy Seeding Spacer Links have the same intended use, design and fundamental scientific technology as the predicate device.

**G. PERFORMANCE DATA SUMMARY:**

The appropriate design verification and validation activities for the modification of the SourceLink™ Brachytherapy Seeding Spacer Links was conducted.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. John C. Knorpp  
Sr. Regulatory Affairs Specialist  
Bard Urological Division  
C. R. Bard, Inc.  
8195 Industrial Blvd.  
COVINGTON GA 30014

Re: K041576  
Trade/Device Name: SourceLink™ Brachytherapy  
Seeding Spacer Links  
Regulation Number: 21 CFR 892.5730  
Regulation Name: Radionuclide  
brachytherapy source  
Regulatory Class: II  
Product Code: 90 KXX  
Dated: June 11, 2004  
Received: June 11, 2004

Dear Mr. Knorpp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

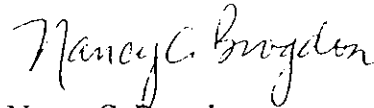
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

1.3 Indications for Use Statement

510(k) Number (if known): \_\_\_\_\_

Device Name: SourceLink™ Brachytherapy Seeding Spacer Links

Indications for Use:

SourceLink™ Connectors are indicated for use in seed spacing and linking in brachytherapy procedures.

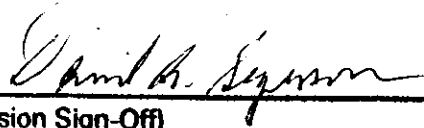
(PLEASE DO NOT WRITE BELOW THIS LINE –  
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR Over-The-Counter Use \_\_\_\_\_

(Optional Format 1/2/96)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K041576